

COST PER RESPONSE, REMISSION AND ENDOSCOPIC IMPROVEMENT OF ADVANCED THERAPIES FOR BIO-EXPOSED PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC) IN FRANCE

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OBJECTIVE

To assess the cost per event of advanced therapies after induction and maintenance in bio-exposed patients with moderately to severely active UC in France

CONCLUSIONS



In addition to providing a new treatment option for bio-exposed adults with moderately to severely active UC, upadacitinib has the lowest cost per event and thus provides savings from a health insurance perspective



These results may be useful to optimize the therapeutic management of bio-exposed adults with moderately to severely active UC in France from a cost-effectiveness point of view

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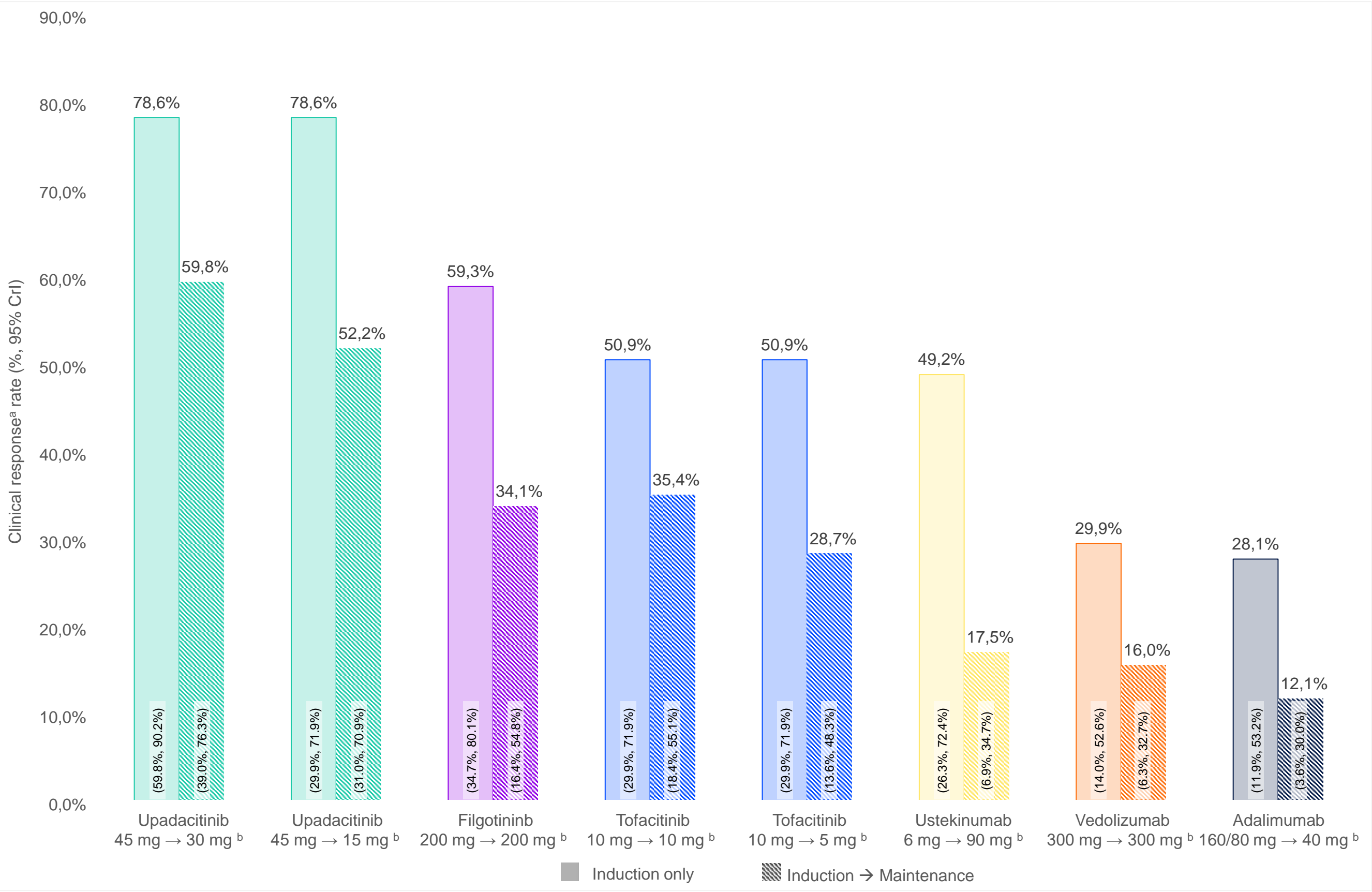
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INTRODUCTION

- Ulcerative colitis (UC) is an idiopathic, chronic, inflammatory disease affecting the colon. Patients with UC have mucosal inflammation starting in the rectum that can extend continuously to proximal segments of the colon¹
- The goals of therapeutic management are clinical remission without steroids and mucosal healing in the long term^{2,3,4}
- Advanced therapies available in France are vedolizumab, tofacitinib, ustekinumab and tumor necrosis factor inhibitors.^{5,6,7} Upadacitinib and filgotinib are not reimbursed for UC at this time in France

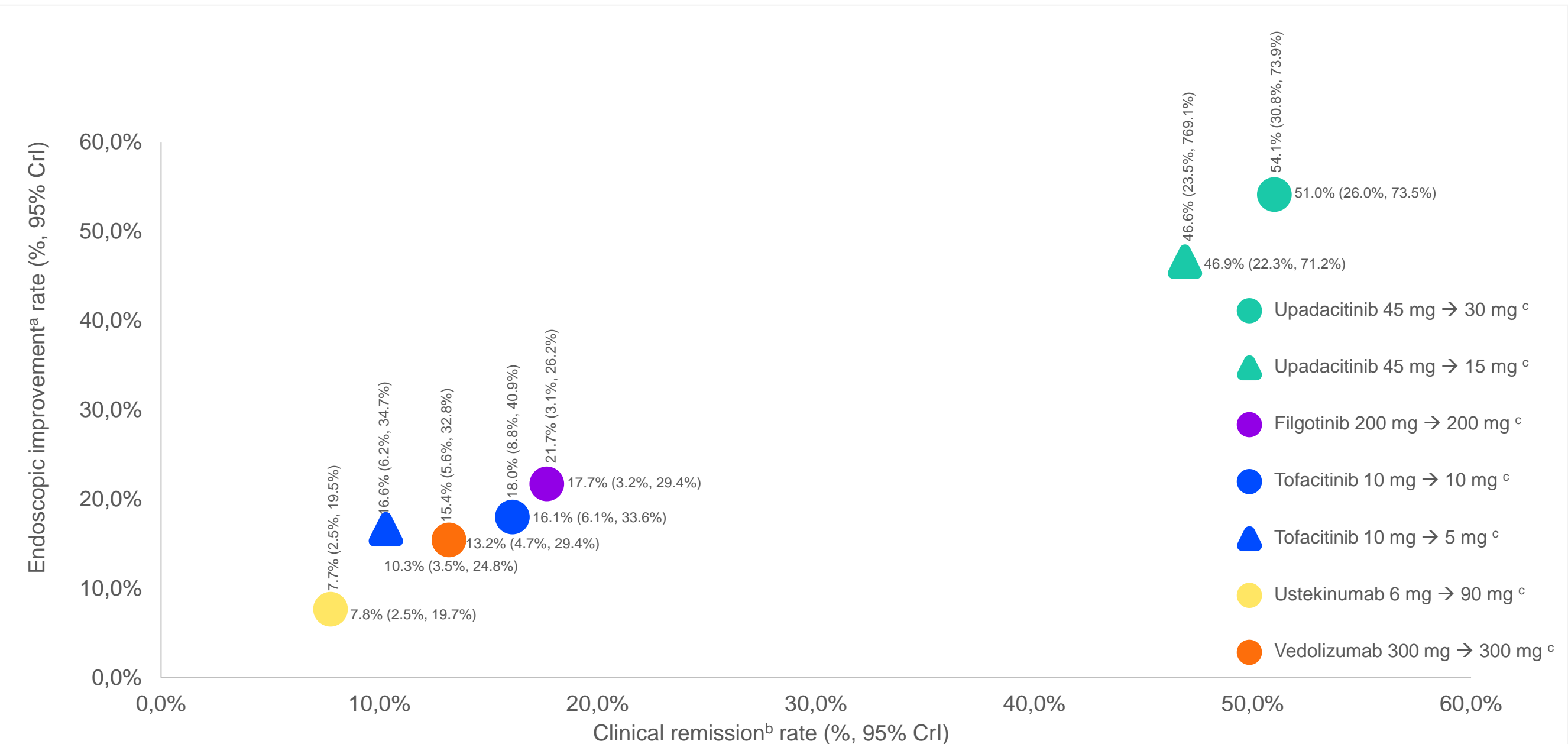
RESULTS

Figure 1. Upadacitinib presents the highest clinical response rates after induction and maintenance treatment (NMA results)



*Clinical response defined as decrease from baseline in Full Mayo score ≥3 points and ≥30%, accompanied by a decrease in Rectal Bleeding Score (RBS) of ≥1 or an absolute RBS of ≥1. *Induction → maintenance dosage. Dosages considered correspond to that of SmPC. Placebo rates for these analyses were 21.3% (12.4%, 34.1%) for the bio-experienced NMA. No data are available for infliximab and golimumab in the bio-experienced population. Dosages considered correspond to that of SmPC. The products listed here are not interchangeable. They differ with respect to mechanisms of action, modes of administration, ingredients, strength, dosage and administration, efficacy, and safety. No conclusions regarding comparative safety or efficacy can be drawn from this information. Consult an individual product's SmPC for full details. CrI, credible interval; SmPC, Summary of Product Characteristics.

Figure 2. Upadacitinib presents the highest clinical event rates after induction and maintenance treatment (NMA results)

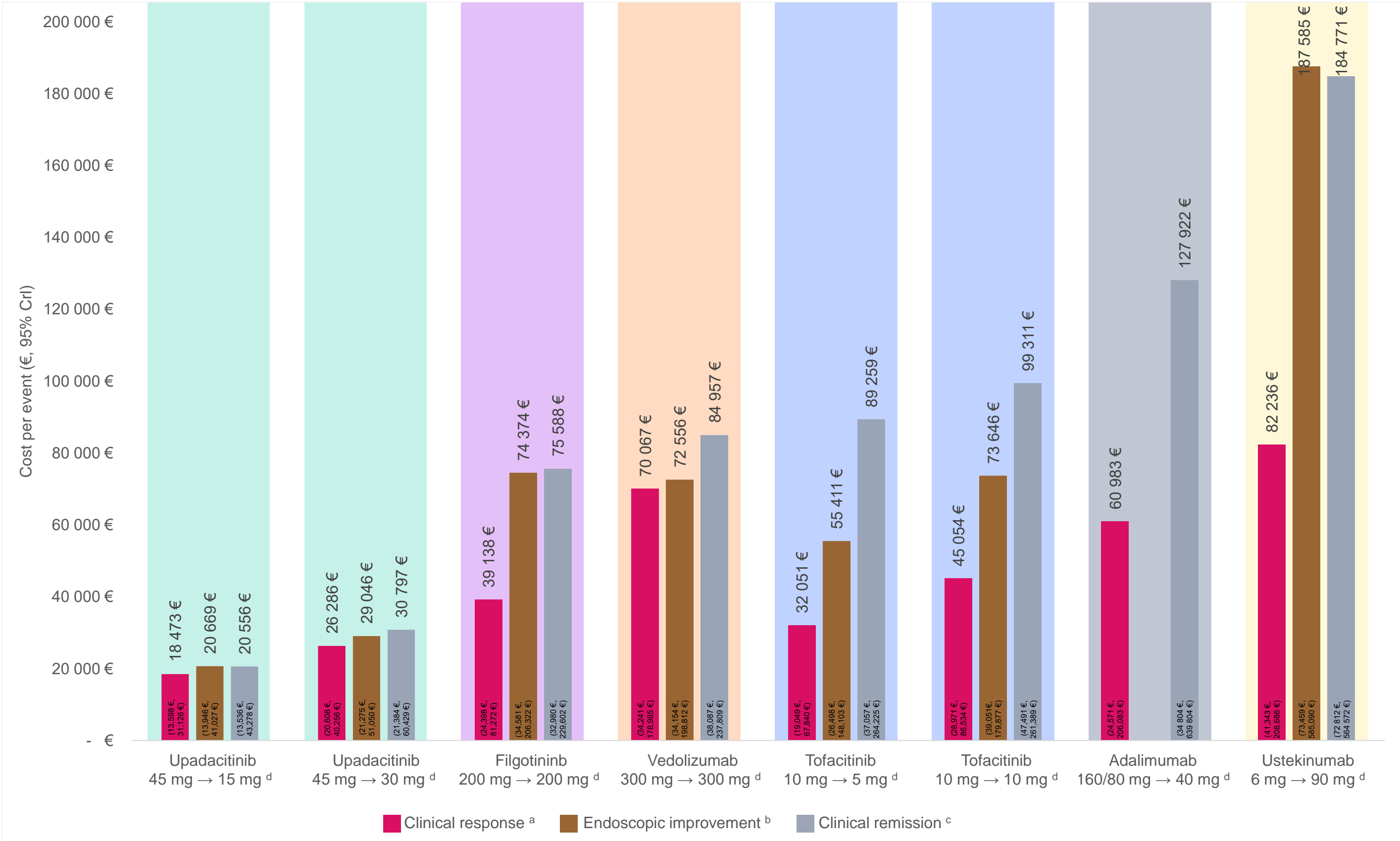


*Endoscopic improvement defined as a Mayo endoscopic subscore ≤1. *Clinical remission defined as a Full Mayo score ≤2 with no subscore >1. *Induction → maintenance dosage. Dosages considered correspond to that of SmPC. Placebo rates for endoscopic improvement outcome analyses were 2.9% (1.4%, 5.7%) for the bio-experienced NMA. Placebo rates for clinical remission outcome were 1.9% (1.0%, 3.7%) for the bio-experienced NMA. No data are available for infliximab and golimumab in the bio-experienced population. No data for adalimumab were available for endoscopic improvement outcome from the clinical trial. Adalimumab rate for the clinical remission outcome (%; 95% CrI) were 5.8% (1.2%, 21.2%). The products listed here are not interchangeable. They differ with respect to mechanisms of action, modes of administration, ingredients, strength, dosage and administration, efficacy, and safety. No conclusions regarding comparative safety or efficacy can be drawn from this information. Consult an individual product's SmPC for full details. CrI, credible interval; SmPC, Summary of Product Characteristics.

METHODS

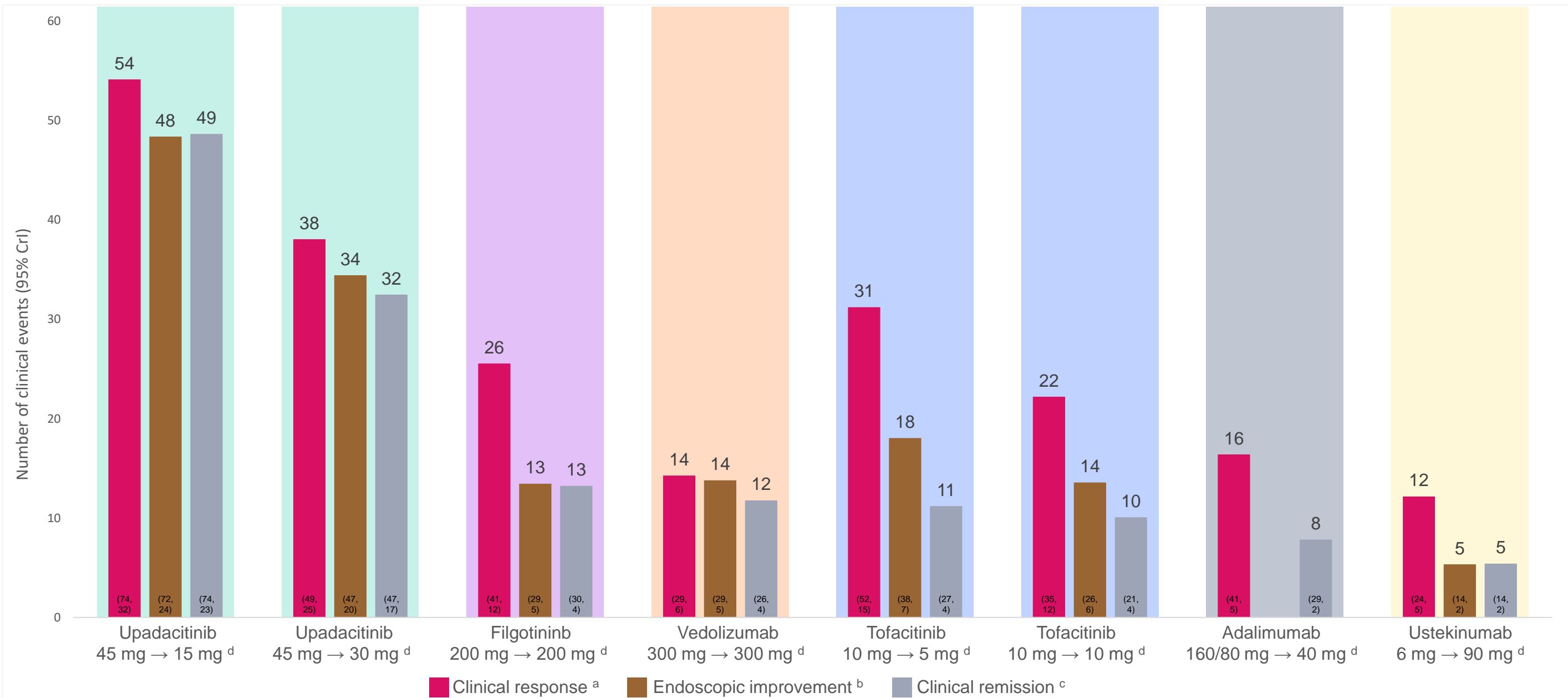
- The cost per event was calculated as treatment cost divided by efficacy rate
- A Bayesian Network Meta-Analysis (NMA) determined the comparative efficacy of advanced therapies using a treat-through approach that adjusted maintenance outcomes by the likelihood of clinical response after induction
- Efficacy outcomes included the proportion of induction responders with clinical response, clinical remission or endoscopic improvement after maintenance
- Drug acquisition costs over one year were derived from French reimbursement lists, except for upadacitinib 45 mg, for which the German published price was used (pre-AMNOG)

Figure 3. At week 52, upadacitinib has the lowest cost to achieving and maintaining clinical events



*Clinical response defined as decrease from baseline in Full Mayo score ≥3 points and ≥30%, accompanied by a decrease in Rectal Bleeding Score (RBS) of ≥1 or an absolute RBS of ≥1. *Endoscopic improvement defined as a Mayo endoscopic subscore ≤1. *Clinical remission defined as a Full Mayo score ≤2 with no subscore >1. *Induction → maintenance dosage. Dosages considered correspond to that of SmPC. Treat-through approach: induction responders x maintenance remitters. No data are available for infliximab and golimumab in the bio-experienced population. No data for adalimumab were available for endoscopic improvement outcome from the clinical trial. If the price of adalimumab was adjusted to the biosimilar price, the CPE (median €, 95% CrI) would be 107,403 € (34,804 €, 639,804). The products listed here are not interchangeable. They differ with respect to mechanisms of action, modes of administration, ingredients, strength, dosage and administration, indications, efficacy, and safety. In addition, material differences exist between the safety profiles of these products. No conclusions regarding comparative safety or efficacy can be drawn from this information. Consult an individual product's SmPC for full details. CrI, credible interval; SmPC, Summary of Product Characteristics. Upadacitinib was also the lowest for clinical response and endoscopic improvement outcomes.

Figure 4. With a budget of 1 M€, upadacitinib achieves the greatest number of clinical events



*Clinical response defined as decrease from baseline in Full Mayo score ≥3 points and ≥30%, accompanied by a decrease in Rectal Bleeding Score (RBS) of ≥1 or an absolute RBS of ≥1. *Endoscopic improvement defined as a Mayo endoscopic subscore ≤1. *Clinical remission defined as a Full Mayo score ≤2 with no subscore >1. *Induction → maintenance dosage. Dosages considered correspond to that of SmPC. No data are available for infliximab and golimumab in the bio-experienced population. The products listed here are not interchangeable. They differ with respect to mechanisms of action, modes of administration, ingredients, strength, dosage and administration, indications, efficacy, and safety. In addition, material differences exist between the safety profiles of these products. No conclusions regarding comparative safety or efficacy can be drawn from this information. Consult an individual product's SmPC for full details. CrI, credible interval; SmPC, Summary of Product Characteristics. Upadacitinib was also the lowest for clinical response and endoscopic improvement outcomes.